Exactech® Equinoxe® Superior/Posterior Augment Reverse Shoulder Glenoid Baseplate
Special 510(k) – 510(k) Summary

Sponsor: Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

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FDA Establishment Number 1038671

Contact: Patrick Hughes
Senior Regulatory Affairs Specialist

JUL 0 3 2013

Date: May 28, 2013

Trade of Proprietary or Model Name(s):
Exactech® Equinoxe® Superior/Posterior Augment Reverse Shoulder Glenoid Baseplates

Common Name:
Reverse Total Shoulder Arthroplasty – Glenoid Components

Classification Name:

Prosthesis, shoulder, semi-constrained, metal/polymer cemented (CFR 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis Class II, Product Code KWS)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade of Proprietary Model Name	Manufacturer
K110708	Equinoxe Reverse Shoulder	Exactech, Inc

Indications for Use:

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi-arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

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Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
√	√		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
√	√		Congenital abnormalities in the skeletally mature
√			Primary and secondary necrosis of the humeral head.
√		√	Humeral head fracture with displacement of the tuberosities
√	√		Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
√	√		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		√	Displaced three-part and four-part upper humeral fractures
	√		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	√		Revision of failed previous reconstructions when distal anchorage is required
√	√		To restore mobility from previous procedures (e.g. previous fusion)
√	√	√	Rotator cuff tear arthropathy

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

Device Description:
The proposed Equinoxe Superior/Posterior Augment Reverse Shoulder Glenoid Baseplates are modifications to augmented Equinoxe reverse shoulder glenoid baseplate devices cleared through premarket notification #K110708.

This submission proposes the following design changes:

1) The proposed device combines a 10° superior augment and an 8° posterior augment previously provided as separate options in the scope of the cited predicate devices

2) The cage peg length is increased to 21.5mm as compared to 17mm for the predicate 10° superior augment glenoid baseplate and 15.7mm for the predicate 8° posterior augment glenoid

Comparison of Technological Characteristics

The predicate and proposed devices have the same intended use and basic fundamental scientific technology. The intended use of the modified device, as described in the labeling, has not changed as a result of the proposed modifications. The modified devices share the following similarities with the predicate devices:

- Indications for use
- Design features (including mating geometry and locking mechanism)
- Material (titanium alloy per ASTM F136)
- 10-year shelf life
- Packaging and sterilization materials and processes (gamma radiation sterilization to a sterility assurance level of 10^{-6}).

The proposed components are not being submitted as the result of a recall or any corrective action related to the Equinoxe product lines.

Non-Clinical Performance Data

Table 1 shows non-clinical performance data provided, cited, or referenced in this submission to support a conclusion of substantial equivalence:

Table 1: Equinoxe Superior/Posterior Augmented Glenoid Testing

Evaluation	Activity
Fixation assessment	Cyclic abduction loosening testing

Substantial Equivalence Conclusion:

Comparison analysis and results of engineering studies referenced in this 510(k) submission demonstrate proposed Equinoxe Superior/Posterior Augment Reverse Shoulder Glenoid Baseplates are substantially equivalent to predicate augmented Equinoxe baseplates cleared through premarket notification #K110708.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 3, 2013

Exactech, Incorporated
% Mr. Patrick Hughes
Senior Regulatory Affairs Specialist
2320 Northwest, 66th Court
Gainesville, Florida 32653

Re: K131575
Trade/Device Name: Exactech® Equinoxe® Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: May 29, 2013
Received: May 31, 2013

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Equinoxe® Superior/Posterior Augment Reverse Shoulder Glenoid Baseplate
Special 510(k) – Indications for Use

510(k) Number: K131575

Device Name: Exactech® Equinoxe® Reverse Shoulder System

INDICATIONS

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Prescription Use___X__	**and/or**	**Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D)		**(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices